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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,167	03/29/2006	Thomas S Bush	8028-007-US	4157

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,167	BUSH ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,12-27,29-41,43,44,46-56 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,9,10,12-27,29-41,43,44,46-56 and 61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7, 9, 10, 12-27, 29-41, 43, 44, 46-56 and 61 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9, 10, 12-27 and 29-31, drawn to a method of using an immortalized human hepatocyte to produce a protein.

Group II, claim(s) 32-34, drawn to a method of using eukaryotic cells other than human hepatocytes to produce a protein.

Group III, claim(s) 35-41, 43 and 44, drawn to an immortalized human hepatocyte cell that includes DNA that encodes and can express a protein.

Group IV, claim(s) 46-50, 56 and 61 drawn to a method of treating a disease or condition comprising administering an active protein produced according to the method of Group I.

Group V, claim(s) 51-55, drawn to a pharmaceutical composition comprising IαIp produced by eukaryotic cells.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically adapted for the manufacture of the said product; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process."

Furthermore, according to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The "Instructions Concerning Unity of Invention" (MPEP, Administrative Instructions Under the PCT, Annex B, Part 1(b)) state, "The expression 'special technical features' is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."

In the instant case, each of the methods of Groups I, II and IV require different elements and/or are directed to obtaining distinct outcomes, which define a special technical feature that is unique to each Group. Specifically, the method of Groups I and II require the use of cells having mutually exclusive properties (i.e., hepatocyte versus not a hepatocyte). In addition, the method of Group IV, which does not require the steps of producing a protein as recited in Groups I and II, requires administering an active protein to a patient suffering from a disease or condition, which steps are not required by the method of Group I or II. As each method comprises a distinct special technical feature, the methods are not so linked as to form a general inventive concept.

Similarly, the products of Groups III and V, directed to a hepatocyte and a pharmaceutical composition comprising IαIp, are structurally and functionally distinct products which do not share a special technical feature.

The methods of Groups I and II are related to the product of Group V in that that the IαIp protein of Group V might be produced by the methods of Groups I or II. However, "[A] process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. (See MPEP 1850 III. A.) As the methods of Groups I and II are not limited to producing an IαIp protein and therefore do not inherently result in the claimed product, the inventions are not so linked as to form a general inventive concept.

The method of Group I is related to the immortalized human hepatocyte of Group III in that the hepatocyte is used in the method. However, immortalized hepatocytes transformed with expression vectors and expressing functional heterologous proteins were known in the art prior to the filing date of the instant application. (See, e.g., Steer et al. WO 01/89579 A2, especially the first full paragraph on page 34. Regarding unity of invention among distinct categories of invention, MPEP 1850 III. A. states, "A single general inventive concept must link the claims in the various categories…" In the instant case, the shared technical feature common to the identified Groups is not a contribution over the art (i.e., not a general inventive concept) therefore there is no unifying special technical feature.

The method of Group II is explicitly limited to using a cell that is distinct from the cell of Group III and the cell of Group III is not made by or used in the method of Group IV. Therefore, the inventions are not linked by shared special technical feature.

Finally, although the pharmaceutical composition of Group V could be used in the method of group IV, pharmaceutical compositions comprising an IαIp produced by eukaryotic cells were known in the art at the time the instant application was filed. (See, e.g., US Patent No. 6,583,108, which contemplates a pharmaceutical composition comprising the IαI protein bikunin. See especially the first paragraph in column 9.) Therefore, there is no unifying special technical feature that unites the inventions of Groups IV and V.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, restriction under 35 U.S.C. 121 and 372 is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The method of Group I, wherein the protein produced a single protein selected from those set forth in claims 7 and 10.

The method of Group II wherein the cell is a single cell type selected from CHO cells, COS cells and yeast cells.

The method of group III, wherein the protein produced a single protein selected from those set forth in claims 41 and 44.

The method of group IV, wherein the protein produced a single protein selected from those set forth in claim 61.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Claims 1 and 6 re generic to the species of claim 7, claim 1 is generic to the species of claim 10, claim 32 is generic to the species of claim 33, claims 35 and 40 are generic to the species of claim 41, claim 35 is generic to the species of claim 44 and claim 56 is generic to the species of claim 61.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are directed to methods of making or using structurally and functionally distinct molecules or cells which, absent an allowable generic claim, define unique special technical features.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning

this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636